(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 June 2001 (21.06.2001)

PCT

(10) International Publication Number
WO 01/45457 A2

(51) International Patent Classification[7]: H04R

(21) International Application Number: PCT/GB00/04701

(22) International Filing Date: 8 December 2000 (08.12.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9929631.1 16 December 1999 (16.12.1999) GB

(71) Applicant and
(72) Inventor: MARSHALL, John, Nicholas [GB/GB]; Flat 4, 6 Lancaster Crescent, Hyndland, GlasgowG12 0RR (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/45457 A2

(54) Title: IMPLANTABLE HEARING AID 1.1

(57) Abstract: A hearing aid, which incorporates a modified electro-dynamic exciter, implanted into the bone of the skull to cause vibration of the bone of the inner ear and the cochlear (inner ear) fluid. The exciter is surgically implanted into the temporal bone. The exciter is modified by encasement in a shell made of titanium or other biocompatible material and is secured in place by drilling a hole in the surface of the mastoid bone, which fits the exciter tightly. Bone cement or osseointegration is used to fix the baseplate of the exciter securely. A microphone, battery, amplifier, volume control, on/off switch and output limiter are also required. Three versions of this design are described. In Type 1 the microphone, battery, amplifier, volume control, on/off switch and output limiter and are externally located and directly connected. In type 2 these components are external and not directly connected, and a radiofrequency transmitter and receiver are employed, and in Type 3 all components are implanted.

IMPLANTABLE HEARING AID 1.1

This implantable hearing aid uses a modified electro-dynamic exciter [1] as the implanted transducer to cause complex vibration of the temporal bone and subsequent vibration of the endolymph and perilymph within the cochlea. This in turn causes vibration of the basilar membrane which is necessary for the generation of the nerve impulses which result in hearing.

The exciter is surgically implanted into the temporal bone (the part of the skull in which the inner ear is located) under local or general anaesthetic.

An electro-dynamic exciter is modified by encasement in a casing made of titanium or other biocompatible material and is secured in place by drilling a hole in the surface of the mastoid bone, which would fit the exciter securely. Bone cement or osseointegration [2] (a process whereby titanium is anchored securely to bone as new bone develops on the surface of the titanium) is used to fix the baseplate of the exciter firmly.
Three different versions of this are described, which will be suitable for different patient requirements and also form a stepwise development program.

Type 1 (Drawing 2) A microphone, battery, amplifier, output limiter volume control and on/off switch are externally located (these could be incorporated into either a ear-worn device looking similar to a conventional hearing aid, or a body worn device allowing greater component weight). There is a direct connection to the transducer via an external coupling located in the skin behind the ear. This would be suitable for patients with severe/profound hearing loss, as higher power would be achieved from an externally worn battery. This would also be the first development stage as the external components would be easily adjusted or altered.

Description

Type 2 (Drawing 3)

The transducer, battery and a radiofrequency receiver are implanted. A microphone, amplifier, battery, output limiter, volume control, on/off switch and radiofrequency transmitter are located externally. This suitable for both moderate and severe hearing loss.

Type 3 (Drawing 4)

All components (microphone, battery, amplifier, transducer, output limiter) are implanted. This would be suitable for patients with a moderate hearing loss, especially those for whom the benefits of having no externally visible components are important.

Description

Background

A *The problems that this design addresses:*

Patients with hearing loss may not benefit from or wish to use a conventional external hearing aid for a number of reasons:

1 Dislike of the appearance of externally worn hearing aids or the stigma associated with wearing an external aid.

2 Chronic ear infection with discharge may be made worse by the earpiece of an external aid, and this discharge may interfere with the functioning of the aid.

3 Physical abnormalities may preclude the use of an external hearing aid.

4 The hearing loss may be too severe to gain benefit from a conventional aid.

B Types of hearing loss

There are two main types of hearing loss, conductive and sensorineural, although some patients may have an element of both. Sensorineural hearing loss is more common. A conductive loss is when there is a problem with the passage of sound through the ear canal and/or middle ear, and the cochlea (organ of hearing) works normally. This type of hearing loss is normally suitable for amplification with a conventional hearing aid, although the problem with the appearance of the hearing aid and associated stigma may apply.

Sensorineural hearing loss is more common. In sensorineural loss the middle ear is normal but the problem lies in the cochlea, auditory nerve or the brain itself. In most cases the cochlea itself is the site of the problem. In these cases the hearing loss may be more severe and the quality of sound

Description

perceived after amplification is often poorer. It is mainly (but not exclusively) for cases of sensorineural loss that implantable hearing aids are targeted.

C Current progress with implantable hearing aids

No fully implantable hearing aids are commercially available at present, although research into implantable hearing aids is ongoing, and some related devices are available (see below). Researchers have to address several problems:

1 Inadequate gain (i.e. inadequate amplification of the sound) so that the benefit is limited.

2 Excessive power requirements making an implantable battery unfeasible unless a rechargeable battery is used. If a rechargeable battery is required, the longer the time between charging the better.

3 Most recent research in developing an implantable hearing aid involve implants that attach to the ossicles (the chain of three bones within the middle ear). These have the disadvantage that the patient's hearing may be made worse by scarring after surgery, damage to the ossicles themselves, or displacement of the implant. This is a particular risk because the ossicles are extremely small and delicate. Removal of the implant may therefore leave the patient with poorer hearing than before implantation, affecting later use of a conventional hearing aid. This design has the potential to address all of the above problems. The gain is high, power consumption low and the middle ear is not affected by the implantation. Removal of the implant should leave the patient with hearing unaffected by the implantation.

D Other related devices

There are two related devices of note that are currently in use.

1 Bone anchored hearing aid. This is similar to a conventional hearing aid but sound is transmitted via an implanted screw, which is inserted into the temporal bone and fixed by osseointegration.

Description 5

The screw is connected to an external mounting, to which the other components are attached. This causes bone vibration and is currently used in cases of conductive hearing loss where middle ear abnormalities or infection preclude the use of a conventional hearing aid. Sound is transmitted to the cochlea by passive vibration of the implanted screw rather than by the use of an implanted transducer.

2 Cochlear Implants. These are only used in cases of profound hearing loss where the patient has no useful hearing even with the most powerful hearing aids. An array of electrodes is inserted into the cochlea itself, allowing direct electrical stimulation of the 'hair cells' in the inner ear. Cochlear implants are very successful in cases of profound hearing loss. although extensive rehabilitation is necessary. Cochlear implants are only suitable in a very small number of cases and are very expensive, as well as causing permanent damage to the inner ear.

E *The electro-dynamic exciter*

In 1991, Ken Herron, working for the DERA (part of the Ministry of Defence) found that composite panels could act as efficient sound radiators. Subsequently, this technology was developed by the UK company NXT (New Transducers Ltd, formerly Verity) who have used the concept to create flat panel loudspeakers. By using one or more *exciters* (typically 15-25mm in size), panels only a few millimetres thick can be made to behave as loudspeakers, with a completely different mode of action to conventional loudspeakers.

This technology also works with curved panels. Different materials have been used to make the panel, and recently the company has announced that totally transparent speakers can be manufactured. I am unaware of any research into the vibration of bone using this technology, or of any design in which the exciter is used other than in the production of different types of loudspeakers. The exciter in this design is *not* being used in a loudspeaker, but is being implanted to cause direct vibration of the bone of the skull, and hence vibration of the inner ear fluids.

References

1 NXT exciter.
Patent number WO9834320
Publication date: 1998-08-06
Inventor(s): AZIMA HENRY (GB); JARVIS EDWARD (GB); ROBERTS MARTIN (GB)
Applicant(s):: NEW TRANSDUCERS LTD (GB); AZIMA HENRY (GB); JARVIS EDWARD (GB); ROBERTS MARTIN (GB) Requested Patent: WO9834320
Application Number: WO1998GB00307 19980130
Priority Number(s): GB19970001983 19970131
IPC Classification: H02K
EC Classification: H04R11/02
Equivalents: AU5874098, EP0956736, NO993719, ZA9800782

2 Osseointegration

Patent Number: US4330891
Publication date: 1982-05-25
Inventor(s): BRANEMARK PER I; THURESSON AF EKENSTAM BO
Applicant(s):: BRANEMARK PER INGVAR; THURESSON AF EKENSTAM BO Requested Patent: CA1157694
Application Number: US19800125654 19800228
Priority Number(s): SE19790002035 19790307 IPC Classification: A61F1/00 ; A61F1/24 EC Classification: A61F2/30L ; A61L27/00H2
Equivalents: AT127680, AT399096B, BE881953, CH653245, DE3007446, DK96880, ES489204, FI800706, FR2450599, GB2045083, IE49186, IT1130275, JP1033180B, JP1838708C, JP5345014, JP55120864, LU82222, NL185390B, NL185390C, NL8001241, NO149373B, NO149373C, NO800651, SE416175, SE7902035

Claims

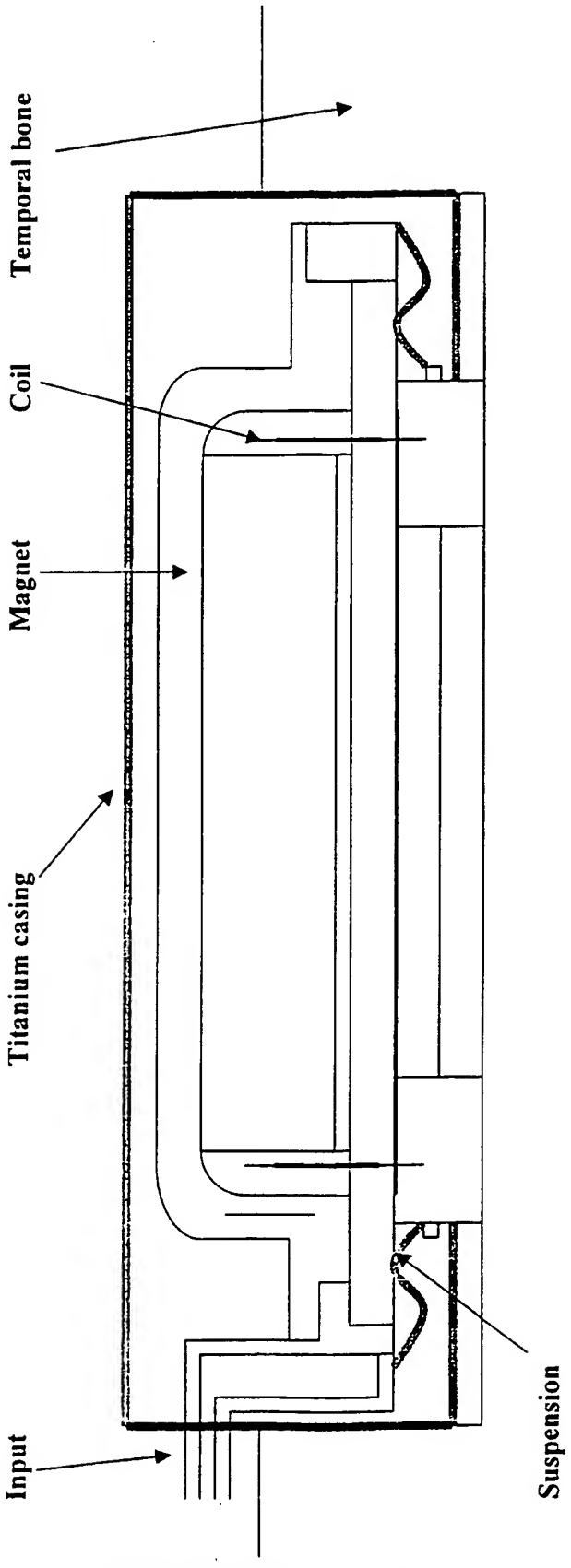
The inventive steps in this design are:

1 the modification of the electro-dynamic exciter by encasing it in titanium to allow biocompatibility without impeding the internal movement of the exciter.

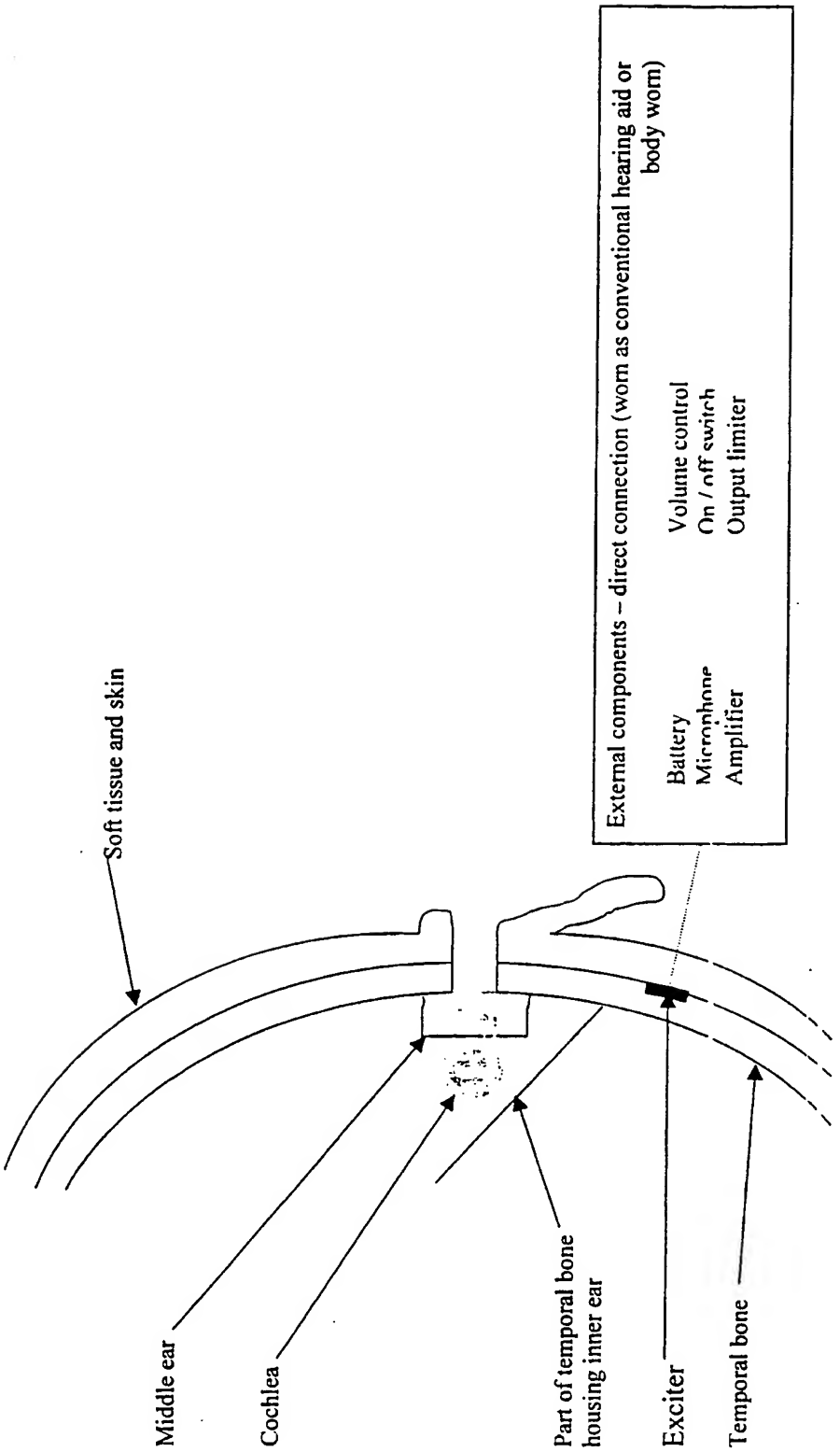
2 the use of this modified exciter as an implanted hearing aid transducer.

3 the use of an exciter as a tranducer to cause bone vibration but not sound radiation.

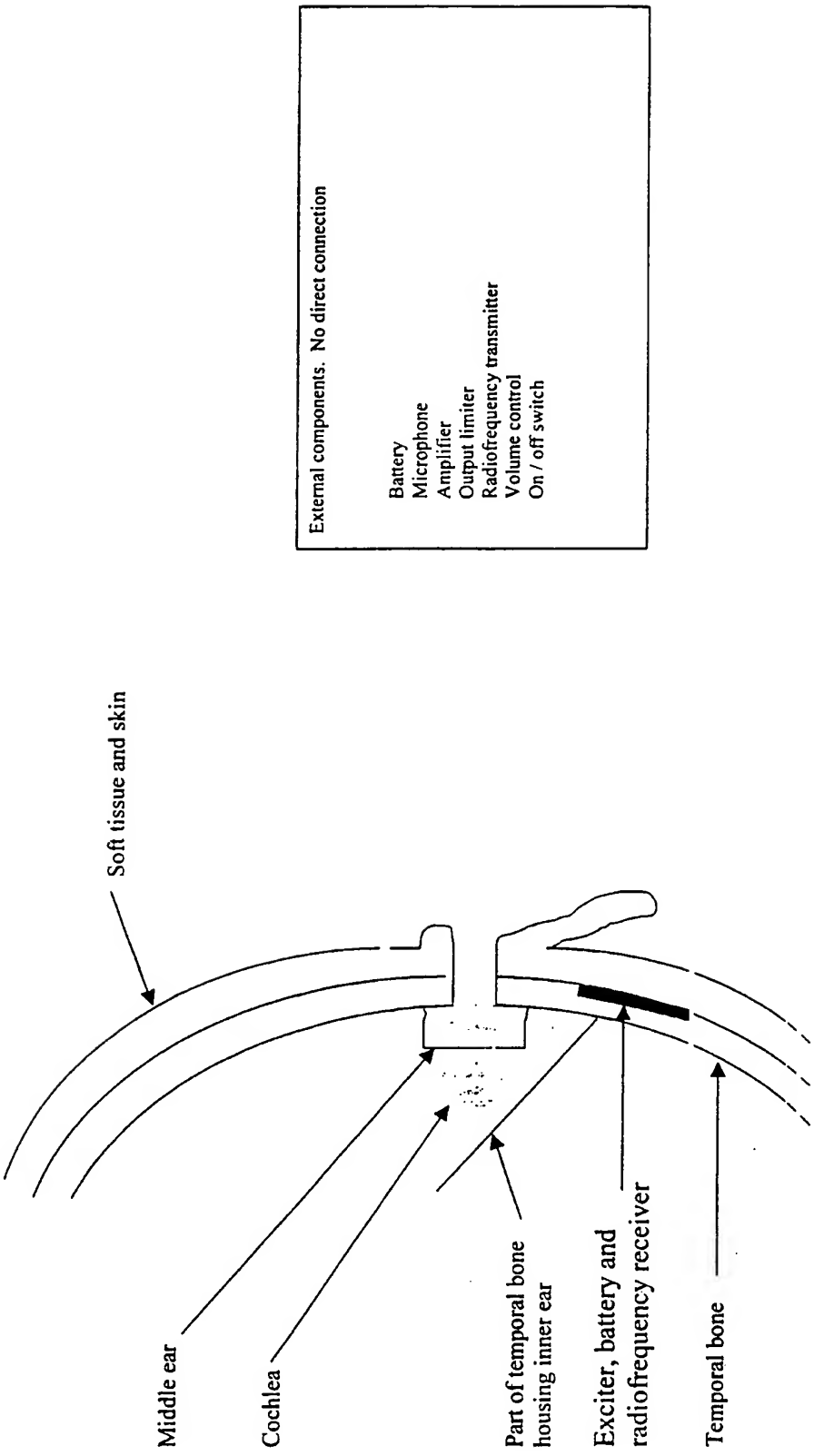
4 the use of a modified exciter in conjunction with other components to create a fully or partially implantable hearing aid.



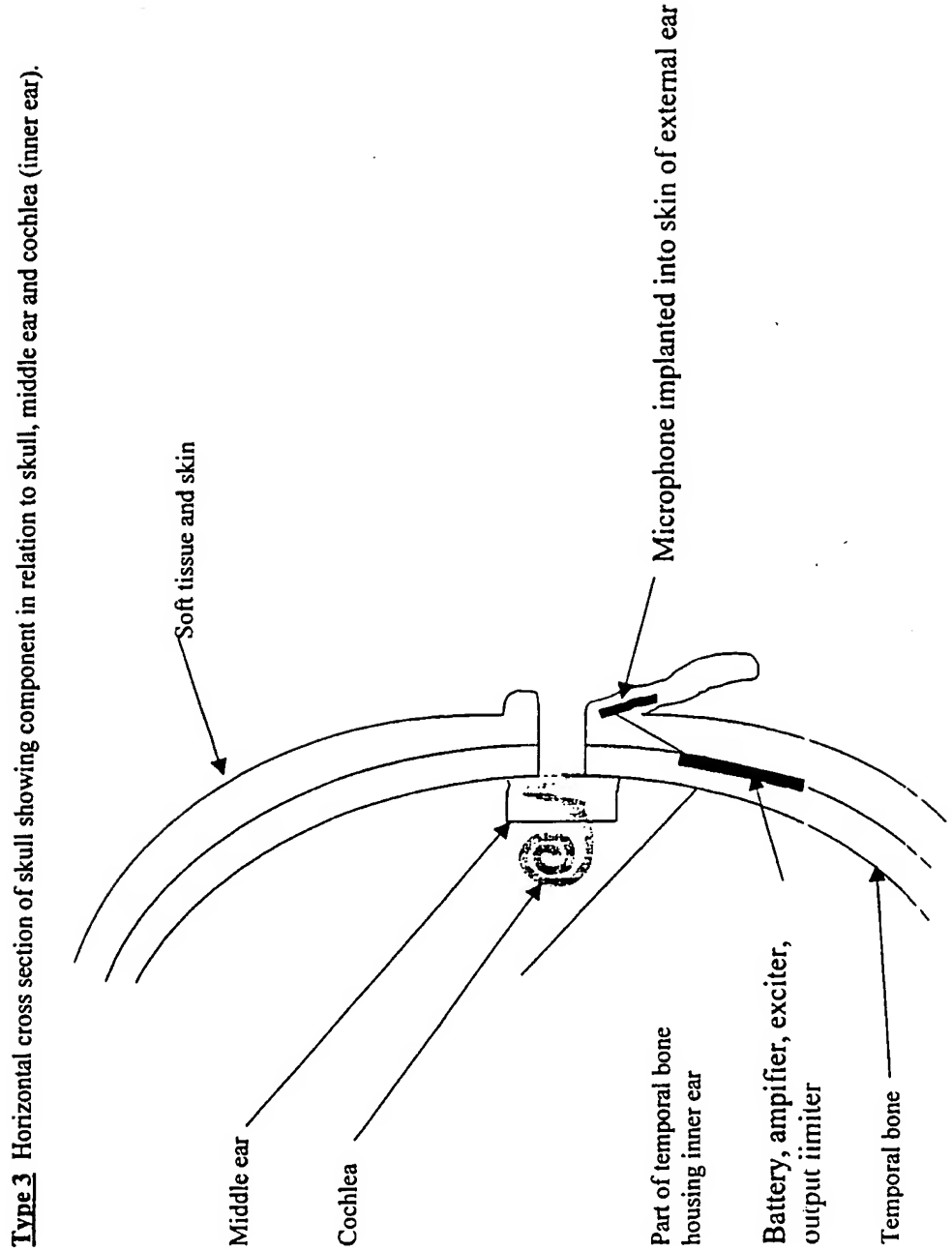
Transducer (exciter) implanted into skull (temporal bone)



Type 1 Horizontal cross section of skull showing component in relation to skull, middle ear and cochlea (inner ear).



Type 2 Horizontal cross section of skull showing component in relation to skull, middle ear and cochlea (inner ear).



Type 3 Horizontal cross section of skull showing component in relation to skull, middle ear and cochlea (inner ear).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 June 2001 (21.06.2001)

PCT

(10) International Publication Number
WO 01/45457 A3

(51) International Patent Classification[7]: H04R 25/00

(21) International Application Number: PCT/GB00/04701

(22) International Filing Date: 8 December 2000 (08.12.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9929631.1 16 December 1999 (16.12.1999) GB

(71) Applicant and
(72) Inventor: MARSHALL, John, Nicholas [GB/GB]; Flat 4, 6 Lancaster Crescent, Hyndland, GlasgowG12 0RR (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

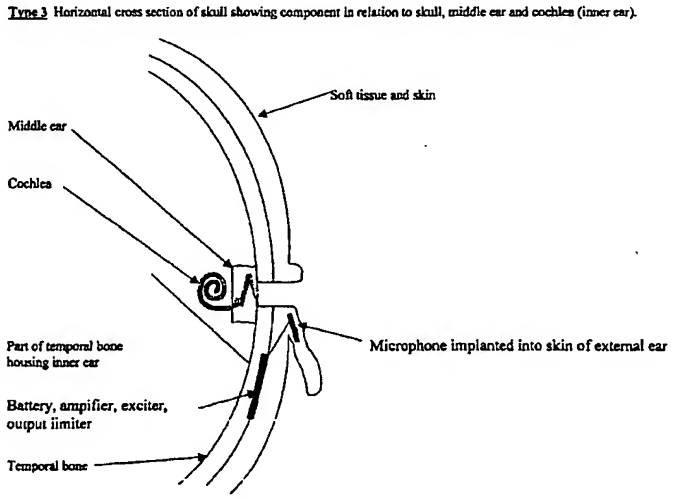
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
27 December 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPLANTABLE HEARING AID 1.1



(57) Abstract: A hearing aid, which incorporates a modified electro-dynamic exciter, implanted into the bone of the skull to cause vibration of the bone of the inner ear and the cochlear (inner ear) fluid. The exciter is surgically implanted into the temporal bone. The exciter is modified by encasement in a shell made of titanium or other biocompatible material and is secured in place by drilling a hole in the surface of the mastoid bone, which fits the exciter tightly. Bone cement or osseointegration is used to fix the baseplate of the exciter securely. A microphone, battery, amplifier, volume control, on/off switch and output limiter are also required. Three versions of this design are described. In Type 1 the microphone, battery, amplifier, volume control, on/off switch and output limiter and are externally located and directly connected. In type 2 these components are external and not directly connected, and a radiofrequency transmitter and receiver are employed, and in Type 3 all components are implanted.

WO 01/45457 A3

INTERNATIONAL SEARCH REPORT

Interi nal Application No
PCT/GB 00/04701

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 H04R25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 H04R A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 612 915 A (HOUGH JACK V D ET AL) 23 September 1986 (1986-09-23) column 2, line 39 -column 3, line 7 column 3, line 42-62 column 4, line 42 -column 6, line 49 ---	1-4
Y	WO 99 31933 A (SYMPHONIX DEVICES INC) 24 June 1999 (1999-06-24) page 1, line 8-10 page 2, line 32-35 page 6, line 3 -page 9, line 37 ---	1-4
Y	US 5 498 226 A (LENKAUSKAS EDMUNDAS) 12 March 1996 (1996-03-12) abstract column 1, line 6-12 column 2, line 59 -column 3, line 55 --- -/--	1-4

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 July 2001	03/08/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Zanti, P

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interr. nal Application No
PCT/GB 00/04701

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 936 840 A (AWENGEN DANIEL F) 18 August 1999 (1999-08-18) column 2, line 4 -column 3, line 12	1-4

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern ıal Application No
PCT/GB 00/04701

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4612915 A	23-09-1986	AU 593251 B	08-02-1990
		AU 5780386 A	27-11-1986
		BE 904809 A	15-09-1986
		CA 1251274 A	14-03-1989
		DE 3617089 A	27-11-1986
		DK 238086 A	24-11-1986
		ES 555252 D	16-07-1987
		ES 8707067 A	16-09-1987
		FR 2582216 A	28-11-1986
		GB 2176078 A,B	10-12-1986
		IL 78724 A	21-06-1992
		IT 1189678 B	04-02-1988
		JP 1839181 C	25-04-1994
		JP 5052747 B	06-08-1993
		JP 61273100 A	03-12-1986
		NL 8601286 A	16-12-1986
		SE 468374 B	21-12-1992
		SE 8602251 A	24-11-1986
WO 9931933 A	24-06-1999	US 6093144 A	25-07-2000
		AU 1811899 A	05-07-1999
		EP 1060638 A	20-12-2000
US 5498226 A	12-03-1996	NONE	
EP 0936840 A	18-08-1999	US 6099462 A	08-08-2000